VEGA TECHNOLOGIES, INC.

510(K) SUMMARY

SEP - 8 2004

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K041516

1. Submitter's Identifications:
   Establishment:
   DONGGUAN DALANG VIGOR ELECTRONICS MFY.
   Yang Wu District, Da Lang Town, Dong Guan City
   Guang Dong Prov., CHINA
   Registration Number: 9616843
   Operations: Manufacturer
   Status: Active
   Date Of Registration Status: 2004

   Owner/Operator:
   VEGA TECHNOLOGIES, INC.
   11F-13, 100 Chang-Chun Rd.,
   Taipei CHINA (Taiwan) 104.
   Owner/Operator Number: 9036509

   Contact:
   Mr. Joseph Lu
   VEGA TECHNOLOGIES, INC.
   I1F-13, 100 Chang-Chun Rd. Taipei, CHINA (TAIWAN) 104
   Phone: 886-2-2541-6996
   Fax: 886-2-2521-3803

2. Name of the Device:
   VEGA Digital Thermometer, models MT-XX8 and MT-XX9.

3. Information of the 510(k) Cleared Device (Predicate Device):
   ST8631 (K021048).

4. Device Description:

   The Digital Thermometers, models MT-XX8 and MT-XX9, are the electronic thermometers by using a thermistor as the temperature sensor. The signal of sensor is calculated and displayed by an ASIC (Application Specific IC) – controlled circuit, which is considered the hard-wire control instead of programmable control. Basically MT-XX8 and MT-XX9 have the same intended use and operation function except for the different measuring range caused by some small different design in IC circuit.

From the construction point of view, the digital thermometer comprises of a thermistor for measuring sensor, a reference resistor for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

This system uses a 1.5V DC battery for operation of complete system whenever the battery is low, the ASIC circuit will detect the low battery condition automatically, and displays 'Low battery' in LCD display. Regarding the performance of MT-XX8 and MT-XX9, it was designed and verified according to the US standard ASTM E1112-98.

5. Intended Use:

The Digital Thermometer, models MT-XX8 and MT-XX9 are the battery-operated electronic devices with intended use of measuring human body temperature precisely. It can be used in the measurement of oral, axially and rectal temperature.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The Digital Thermometer, models MT-XX8 and MT-XX9 are substantially equivalent to the Mesure model ST861 (K021048).

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
Compliance to applicable voluntary standards includes ASTM E1112: 1998, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

8. Conclusions
The VEGE Digital thermometer, including MT-XX8 and MT-XX9, have the same intended use and technological characteristics as the cleared device of Mesure model ST8631 (K021048). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Mr. Joseph Lu
General Manager
Vega Technologies, Incorporated
11F-13, 100, Chang-Chun Road,
Taipei CHINA (TAIWAN) 104

Re: K041516
Trade/Device Name: Digital Thermometer/ Models MT-XX8 and MT-XX9
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: August 21, 2004
Received: August 27, 2004

Dear Mr. Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

cisely.

510(k) Number (if known): K041516

Device Name: Digital Thermometer / Models MT-XX8 and MT-XX9.

Indications For Use:

The Digital Thermometer, models MT-XX8 and MT-XX9 are the battery-operated electronic devices with intended use of measuring human body temperature precisely. It can be measurement of oral, axially and rectal temperature.

Prescription Use _____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K041516